

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application. No.	:	10/540,632
Confirmation. No.	:	2574
Applicant(s)	:	Yumimitsu Suda et al.
Filed	:	23 June 2005
Title	:	Oily External Composition for Skin
TC/A.U.	:	1616
Examiner	:	Danielle D. Sullivan
Docket No.	:	IWI-16057

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPEAL BRIEF**

Sir:

This Appeal Brief is being filed in response to the Office Action of 23 November 2009 and pursuant to the Notice of Appeal filed 8 February 2010.

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## **I. REAL PARTY IN INTEREST**

The real party in interest or owner of the present application and the technology and inventions embodied therein is Shiseido Co., Ltd., whose principal mailing address is 5-5 Ginza, 7-chome, Chuo-Ku, Tokyo, Japan 104-8010. An assignment transferring rights from the inventors to Shiseido Company was recorded 12 July 2005 at Reel 016509, Frame 0859.

## **II. RELATED APPEALS AND INTERFERENCES**

None.

### III. STATUS OF CLAIMS

The application included 12 claims as originally filed on 23 June 2005. In a Preliminary Amendment filed together with the application, minor amendments were made to claims 1, 3-5, and 7-11, with no claims canceled or added. Claims 1-12 were pending thereafter.

In a first Office Action mailed on 29 November 2007, the Examiner rejected claims 1-12 under 35 U.S.C. 112, second paragraph; claims 1-12 under 35 U.S.C. 102(b) over the Nakane reference, and claims 10 and 11 under 35 U.S.C. 101.

In an Amendment filed 28 May 2008, claim 2 was canceled, claims 1, 3, 8, and 10-12 were amended, and no claims were added, leaving claims 1 and 3-12 remaining.

In an Office Action mailed 17 September 2008, claims 1 and 3-12 were finally rejected under 35 U.S.C. 112, second paragraph and for double patenting over U.S. Pat. App. Pub. No. 2004/0175386 to Yoshikawa et al., ("Yoshikawa") in view of Nakane. Claims 1 and 3-12 were separately rejected under 35 U.S.C. 102(b) over Nakane.

Appellants filed Amendment "C" on 15 December 2008 canceling claims 3-6 and amending claims 1 and 10-12. No claims were added, leaving claims 1 and 7-12 pending, which claims remain pending through this writing. An amendment to paragraph 49 of the specification was supported by the Declaration of Yuji Iwahashi, filed together with Amendment C. A Terminal Disclaimer was filed relative to Yoshikawa.

In an Advisory Action mailed 23 January 2009, the Examiner refused to enter Amendment C, and especially the amendment to paragraph 49, stating that such was new matter, and that the Amendment failed to place the Application in condition for allowance. The Examiner requested a certified copy of the translated PCT priority document to support the specification amendment based on a corrected translation.

On 16 March 2009, Appellants filed Amendment D together with a Request for Continued Examination, repeating the subject matter of the previous amendment. A substitute specification was filed to show the changes based on the corrected translation, together with a statement (Declaration) of Kanako Ohtsuka, certifying the accuracy of the corrected translation.

On 5 June 2009, the Examiner mailed an Office Action rejecting claims 1 and 7-12 under 35 U.S.C. 103(a), both (1) over Nakane in view of Kobayashi and (2) over Kobayashi in view of Nakane.

In an Interview of 1 July 2009, the undersigned discussed with Examiners Sullivan and Richter the removal of the objection to the specification amendment of paragraph 49 based on the Declarations filed 15 December 2008 and 16 March 2009. The Examiners requested a certified translation of the priority document (PCT/JP2003/16952) to be submitted to ensure that specification amendments were consistent with the certified translation.

Appellants filed Amendment "E" on 27 August 2009, in which claims 1 and 12 were amended, no claims were deleted or added, leaving claims 1 and 7-12 pending. A certified copy of the translation of the priority PCT Document (JP2003/16952) was filed.

The Examiner mailed an Office Action on 23 November 2009 finally rejecting claims 1 and 7-12 under 35 U.S.C. 103(a) over the Nakane and Kobayashi references, and under 35 U.S.C. 112, first paragraph.

On 8 February 2010, Appellants filed a Notice of Appeal, because there is at least one actual issue for appeal.

In summary, claims numbering as high as 12 have at one point been pending in the application. During the prosecution thus far, claims 2-6 have been canceled, leaving claims 1 and 7-12 pending as of this writing.

Claims 1 and 7-12 stand finally rejected, and all such claims are pending on appeal. The pending claims are set forth in the Claims Appendix, which is attached hereto for the convenience of the Board.

#### **IV. STATUS OF AMENDMENTS**

No amendments were filed in the application subsequent to the Office Action mailed 23 November 2009.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

As characterized in the Abstract:

The objective of this invention is to provide an oily external composition for skin having an excellent rough skin recovering/preventing effect, and wherein powder is well dispersed in oil. An oily external composition for skin of this invention is characterized in that comprising a complex powder (the surface of lipophilic base powder is covered with zinc oxide) and an oil component, wherein said complex powder is dispersed in said oil component, and wherein zeta-potential of said lipophilic base powder is negative value at pH on skin. It is preferable that zeta-potential of said lipophilic base powder is -10mV or less at pH on skin. It is preferable that said lipophilic base powder is swelled in the condition of dispersing in oil. Above-mentioned external composition can be used as a rough skin recovering composition and a sensitive skin caring composition.

In the remainder of the Summary, citation formats will follow this format: “page/line,” for example “4/18” and “[paragraph],” for example [0029], with multiple citations for the same limitation separated by a semicolon. Such format is believed to be clear.

In particular, independent claim 1 recites an oily external composition for skin (2/16; [0008]) comprising:

a complex powder including lipophilic base powder and zinc oxide, where the surface of lipophilic base powder is covered with zinc oxide (2/16-18; [0008]); and an oil component (2/18; [0008]);

wherein said complex powder is dispersed (2/20; [0008]) and swelled (2/28; [0010]) in said oil component (2/20 and 28; [0008] and [0010]),

wherein the zeta-potential of said lipophilic base powder is a negative value at pH 7.5 (2/21; [0008] “pH on skin” is pH 7.5), and

wherein the zinc oxide covers from 5 to 50% (14/19-21; [0075]) of the total surface area of said lipophilic base powder dispersed in said oil component, and

wherein the lipophilic base powder is one or more selected from the group consisting of silicone resin, silicone rubber, and silicone resin-covered-silicone rubber (3/1-2; [0011]).

Also, independent claim 12 is directed to a complex powder comprising a lipophilic base powder and zinc oxide (2/16-18; [0008]);



wherein the surface of said lipophilic base powder is covered with zinc oxide (2/17-18; [0008]), wherein the zeta-potential of said lipophilic base powder is a negative value at pH 7.5 (2/21; [0008] “pH on skin” is pH 7.5), wherein zinc oxide covers 5 to 50% (14/19-21; [0075]) of the total surface area of said lipophilic base powder when said lipophilic base powder is dispersed (2/20; [0008]) and swelled (2/28; [0010]) in oil (2/20 and 28; [0008] and [0010]), and

wherein the lipophilic base powder is one or more selected from the group consisting of silicone resin, silicone rubber, and silicone resin-covered-silicone rubber ([0034]).

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Whether claims 1 and 7-12 stand properly rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent Number 5,122,418 to Nakane et al., (“Nakane”) in view of U.S. Patent Number 5,928,660 to Kobayashi, et al., (“Kobayashi”).

2. Whether claims 1 and 7-12 stand properly rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

## **VII. ARGUMENT**

### **A. Claims 1 and 7-12 (Grouped) Were Improperly Rejected Under 35 U.S.C. § 103(a) over a combination of the Nakane and Kobayashi references.**

The Examiner has rejected claims 1 and 7-12 are under 35 U.S.C. §103(a) as obvious over the Nakane and Kobayashi references.

Such rejection is principally based on the Examiner's belief that Nakane discloses a composition for protecting skin from the sun comprising a complex powder including a lipophilic base powder and zinc oxide. The surface of the base powder is covered with zinc oxide. An oil component is also present. The Examiner cites example 25 therein for the preceding allegations. The Examiner admits that Nakane fails to disclose that the lipophilic base powder is selected from the group consisting of silicone resin, silicone rubber and silicone resin-covered-silicone rubber. Kobayashi is accordingly cited.

The Examiner believes that Kobayashi teaches a cosmetic including powdered silicone rubber, citing the Abstract. At column 3, lines 8-23, the Examiner cites Kobayashi as disclosing an aqueous suspension of a powdered silicone rubber including a non-crosslinked oil (less than 80%, preferably less than 50%, 4/56-63), to impart a softening feeling to skin and improve cosmetic durability because the oil swells the silicone rubber. Inorganic powders such as zinc oxide (5/9 and 21-41) may cover the silicone rubber to impart stability (4/64-67).

With respect to the Kobayashi reference, the cosmetic raw material disclosed therein includes an aqueous suspension of a powdered silicone rubber with a mean particle size of 0.1 to 500 microns (a 5000 fold difference in from the top to the bottom boundary of that range.) The aqueous suspension of powdered silicone rubber therein is obtained by curing a silicone rubber composition dispersed in water in the form of fine particles containing a non-crosslinked oil. This means the powdered silicone rubber contains oil at the time of being produced as particles for cosmetics. The powdered silicone rubber as disclosed by Kobayashi may have swelled because it is impregnated by a non-cross-linked oil during its production process (column 3, lines 8-23).

Claims 1 and 12 now recite that the zinc oxide covers the lipophilic base powder at a rate of 5 to 50% of the total surface area of the lipophilic base powder which is dispersed in an oil component. This range is supported in the specification in tables 8 and 9. Within this covering

rate range, the dispersibility in oil is good, and the effect on treating rough skin is excellent. This amendment alone removes the claimed subject matter from the purview of the cited Nakane and Kobayashi references, in any combination.

The Examiner appears to equate the weight percentages in various of Nakane's examples with surface area covering percentages as instantly claimed. This interpretation is not supported by the disclosures of Nakane. Indeed, looking to Example 7 of Nakane, it is clear that "40% titanium oxide covered spherical cellulose," means 40% by weight. Indeed, Nakane discloses, at column 16, lines 7-12 (caption to Example 7):

In the same way as in Example 1, 60 parts of spherical cellulose powder (average particle size 20 microns) were mixed with 40 parts of titanium dioxide powder (average particle size 0.2 micron) in a Henschel mixer for 5 minutes, then the obtained mixed powder was mixed and compressed in a vibration ball mill charged with alumina balls (Nippon Kagaku Tokyo Co., HD alumina balls, 2 mm  $\Phi$ ) for 20 hours.

Considering above description, it can be understood that "40%" represents the weight percentage of titanium dioxide in the complex powder. Further evidence that Nakane's convention with respect to percentages refers to weight (and not surface area covering rate) can be found in the asterisked footnotes for examples 8-11, found immediately beneath the respective formulation tables. It is thus clear, that the Examiner's citation of Nakane's Example 25 refers to a covered powder having 30% by weight of zinc oxide and 70 % by weight of polymethyl methacrylate.

Returning the focus to the surface area coverage rate, the broad and narrow teachings, of Nakane, for example in the first paragraph of the specification, point to:

A composite powder wherein the surface of one type of core powder is **substantially completely covered** with another type of coating powder, thereby improving the surface characteristics of the powder.

(emphasis supplied).

Indeed, the phrase "substantially completely" appears 24 times in the specification and claims of Nakane, in reference to the covering rate of a core powder by one or more types of organic, inorganic or metallic powders. Accordingly, the skilled artisan finds absolutely no

motivation or suggestion therein to cover a core powder at a rate anything less than “substantially completely.”

The Examiner has argued that “substantially completely” is a relative term, hence indefinite, and cannot be used as a point by which the presently claimed invention can be distinguished over Nakane.

Appellants concede that “substantially completely in Nakane is not clearly defined. However, it is readily discernible by the skilled artisan from a study of Figures 1-3 that “substantially completely” is come value very near to 100%. How near to 100% we need not say, however it is certainly much higher than the range of 5-50%, as instantly claimed. Appellants invite the Board to consider that “substantially completely” is not a limitation of an instant claim, but rather a disclosure of the Nakane prior art document. The metes and bounds of the instant claim (5-50% covering rate) are clear, and sufficiently distinguished from the prior art of Nakane in an unambiguous way. There is no overlap between “substantially completely” and 5-50%.

In addition, because Nakane relates largely to a “sunburn preventing lotion,” (there are 38 instances of the phrase “sunburn preventing” therein) the skilled artisan immediately recognizes that zinc oxide is used as a sunscreen agent. Experimental Example 25 is one specific instance of the invention of Nakane used as a sunscreen. It is therefore unlikely that the skilled artisan following the teachings of Nakane to produce a sunscreen would reduce the covering rate of zinc oxide to the range of 5-50% of the surface area of the base powder. Higher zinc oxide content leads to a better suncreening effect, which would be the only goal of a sunscreen agent.

Additionally, the silicone oil component of Example 25 does not correspond to the silicone resin and/or silicone rubber base powders instantly claimed. Further, the core powder of Nakane is not a swelling powder. As noted in paragraph 49 of the instant specification (as amended), the powders employed by Nakane, such as polyamide (nylon) and polymethyl methacrylate, are not swelling powders. Hence, Nakane fails to disclose a powder that is both lipophilic and that swells in oil.

The instantly claimed base powders, selected from silicone resin, silicone rubber, and silicone resin-covered-silicone rubber, are swellable in oil, and as such, can adsorb a plasminogen activator, as shown in Figure 1, and as disclosed in at least paragraphs [0007],

[0019], and [0027] of the specification. Nakane further fails to disclose the limitation that the base powder is swelled in oil. Nakane fails to disclose that the base powder is silicone resin, silicone rubber, or silicone resin-covered- silicone rubber.

Although the powdered silicone rubber is produced as an aqueous suspension, Kobayashi also disclosed the powder as being devoid of water content and it has been blended with oil components to produce cosmetics. Therefore, Kobayashi teaches impregnating the powdered silicone rubber with oil and blending the oil-swelled silicone rubber into an oily external composition.

However, Kobayashi fails to teach or disclose covering the powdered silicone rubber with zinc oxide at a surface area covering rate of 5-50%. Kobayashi discloses a powdered silicone rubber whose surface is covered with a fine inorganic powder. The fine inorganic powder could be zinc oxide, and it is used to provide the powdered silicone rubber with good dispersibility and the capacity to absorb ultraviolet radiation. Higher dispersibility and UV absorption are achieved by higher covering rates, (a lower covering rate allows the silicone rubber particles of Kobayashi to agglomerate). Therefore, the skilled artisan does not learn from Kobayashi a covering rate of 5-50%.

Also, the complex powder of the present invention cannot be derived from Kobayashi's method for covering a silicone rubber powder with fine inorganic powder (zinc oxide). Kobayashi discloses a method of adding a fine organic powder (zinc oxide) to an aqueous suspension of a powdered silicone rubber, and the surface of the powdered silicone rubber is coated with this fine inorganic powder under agitation. "Powdered silicone rubber" in this method is an oil-impregnated powder, that is: the powder was previously swelled with oil before it was coated with the fine organic powder. Accordingly, in Kobayashi's method, zinc oxide would uniformly and completely cover the surface of the swelled powdered silicone rubber. Nothing in Kobayashi leads to another conclusion relative to covering rate.

Further, although Kobayashi has disclosed cosmetics where the powdered silicone rubber (devoid of water) is blended with oil components, these are Comparative Examples, which represent the prior art which Kobayashi is trying to overcome and surpass. Hence, a reading of Kobayashi does not lead one to practice the subject matter taught in its comparative

examples. The skilled artisan finds no motivation to combine prior art references based on their comparative examples.

On the other hand, in the presently claimed complex powder, a lipophilic base powder (silicon rubber) must be dispersed into oil components. This leads to the specific covering rate of 5-50% because of oil-swelling the base powder as shown in Figure 1. Thus, the oily external composition of the present invention contradicts the intent of Kobayashi, so it is impossible for one skilled in the art to derive the present invention from Kobayashi's teaching.

Indeed, neither Nakane nor Kobayashi individually leads the skilled artisan to cover a base powder with 5-50% (by surface area) of zinc oxide. This teaching comes only from Appellants' disclosure. Therefore, this does not mean the claimed subject matter is obvious, rather it is indicative of invention.

Based on the foregoing, Appellants respectfully request that the Board overturn the rejection of claims 1 and 7-12 over Nakane and Kobayashi.

**B. Claims 1 and 7-12 were improperly rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.**

Claims 1 and 7-12 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner believes that the limitation "the zinc oxide covers from 5 to 50% of the total surface of said lipophilic base powder," is not supported in the specification. The Examiner admits that the specification supports the range 1-90% coverage, in paragraph [0096].

The Examiner "bears the initial burden . . . of presenting a prima facie case of unpatentability." In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." Wertheim, 541 F.2d at 263, 191 USPQ at 97.

In their Amendment E, filed 27 August 2009, Appellants invited the "Examiner [to] note that claims 1 and 12 have been amended to recite that the zinc oxide covers the lipophilic base powder at a rate of 5 to 50% of the total surface area of the lipophilic base powder which is

dispersed in an oil component. This range is supported in the specification in tables 8 and 9.”

Perhaps Appellants could have been more explicit in pointing out this support for the newly claimed range in the specification as originally filed. Appellants note that Tables 8 and 9 of the specification (paragraphs 94 and 95) show the properties “dispersibility in oil” and “rough skin recovering effect” for zinc oxide coverage of lipophilic base powders (silicone rubber powder and polyamide powder) at rates of 1, 5, 10, 20, 50, 90 and 100%. The endpoints of the range now found in claims 1 and 12 are explicitly found therein.

Further, as shown in Tables 8 and 9, the property, “Rough skin recovering effect” is clearly better in the coverage range of 5-50% than that at other coverage rates. The evaluation criterion of “rough skin recovering effect” is shown in paragraph [0079] of the specification. According to it, double circles shown by covering rate of 5-50% represent the best effect. That is, in a composite powder of the present invention, covering rate is effective in the range of 1-90%, and more effective in the range of 5-50% in terms of rough skin recovering effect. Another way to say this is that a covering rate of 5-50% is a preferred embodiment of the invention.

MPEP 2163.02 provides an objective standard for determining compliance with the written description requirement namely, whether “the description clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” From the result shown in Tables 8 and 9, it seems that person skilled in the art can recognize that complex powders within a covering rate range of 5-50% have a particularly excellent rough skin recovering effect.

Based on the foregoing, Appellants assert that the covering rate range of 5-50% is amply disclosed and supported in the specification, and respectfully request that the Board overturn the rejection of claims 1 and 7-12.



#### 4. Conclusion

In view of the foregoing, it is respectfully submitted that claims 1 and 7-12 are allowable, and a ruling from the Board to that effect is therefore respectfully requested.

Respectfully submitted,  
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## CLAIMS APPENDIX

Claim 1 (rejected): An oily external composition for skin comprising:

a complex powder including lipophilic base powder and zinc oxide, where the surface of lipophilic base powder is covered with zinc oxide; and an oil component;

wherein said complex powder is dispersed and swelled in said oil component,

wherein the zeta-potential of said lipophilic base powder is a negative value at pH 7.5,  
and

wherein the zinc oxide covers from 5 to 50% of the total surface area of said lipophilic base powder dispersed in said oil component, and

wherein the lipophilic base powder is one or more selected from the group consisting of silicone resin, silicone rubber, and silicone resin-covered-silicone rubber.

Claims 2-6 (cancel)

Claim 7 (rejected): The oily external composition for skin according to claim 1 wherein the oil component comprises silicone oil.

Claim 8 (rejected): The oily external composition for skin according to claim 1 wherein the content of said complex powder is in the range of 1 to 50 % by weight.

Claim 9 (rejected): The oily external composition for skin according to claim 1 wherein said composition is an emulsion.

Claim 10 (rejected): A method of treating rough skin comprising:

applying the composition of claim 1 to rough skin to thereby promote recovering of said rough skin.

Claim 11 (rejected): A method of treating sensitive skin comprising:

applying the composition of claim 1 to sensitive skin to thereby relieve an abnormal feeling associated with said sensitive skin.

Claim 12 (rejected): A complex powder comprising a lipophilic base powder and zinc oxide, wherein the surface of said lipophilic base powder is covered with zinc oxide, wherein the zeta-potential of said lipophilic base powder is a negative value at pH 7.5, wherein zinc oxide covers 5 to 50% of the total surface area of said lipophilic base powder when said lipophilic base powder is dispersed and swelled in oil and wherein the lipophilic base powder is one or more selected from the group consisting of silicone resin, silicone rubber, and silicone resin-covered-silicone rubber.

## **EVIDENCE APPENDIX**

Declaration of Yuji Iwashashi, 5 December 2008, filed 16 March 2009, entered into the record in the Office Action mailed 5 June 2009.

Certification Statement of Kanako Ohtsuka, 20 August 2009, filed 27 August 2009. Entered into the record in the Office Action of 23 November 2009.

Certified translation of priority document, PCT/JP2003/16952, filed 27 August 2009. Entered into the record in the Office Action of 23 November 2009.

## **RELATED PROCEEDINGS APPENDIX**

None.